Exhibit 2

Gynecare
Gynemesh™ PS
Nonabsorbable PROLENE™ Soft Mesh

Nonabsorbable PROLENE™ Soft Mesh
Ikke-resorberbar blød PROLENE™ mesh
Niet-resorbeerbare PROLENE™ soft mesh
Resorboitumaton PROLENE™-verkko
Treillis à maille souple en PROLENE™ non résorbable
Nicht-resorbierbares PROLENE™ Soft-Netz
Μη απορροφήσιμο, μαλακό πλέγμα PROLENE™
Rete morbida non riassorbibile PROLENE™
Rede suave PROLENE™ não absorvível
Malla blanda PROLENE™ no absorbible
Icke resorberbart mjukt nät av PROLENE™
不可吸收PROLENE™软质网片
不可吸收性PROLENE™柔軟網片
비흡수성 PROLENE™ 소프트 메쉬

ETHICON LLC
Highway 183 Km 8.3
San Lorenzo 00754
Puerto Rico
U.S.A.

+1-877-ETHICON
+1-513-337-6928

CE 0086

Made in U.S.A.

ETHICON
Women's Health & Urology

GYNECARE GYNEMESH™ PS
Nonabsorbable PROLENE™ Soft Mesh

ENGLISH

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and could lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. GYNECARE GYNEMESH™ is intended for use only by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction (including abdominal sacrocolposuspension/ sacrocolpopexy) and the implantation of synthetic meshes. The physician is advised to consult the medical literature regarding techniques, complications, and hazards associated with the intended procedures.

INDICATIONS

GYNECARE GYNEMESH™ is indicated for use as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted.

CONTRAINDICATIONS

- GYNECARE GYNEMESH™ should not be used in infants, children, pregnant women, or in women planning future pregnancies, because the mesh will not stretch significantly as the patient grows.
- GYNECARE GYNEMESH™ must always be separated from the abdominal cavity by peritoneum.
- GYNECARE GYNEMESH™ must not be used following planned intraoperative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which could lead to infection that may require removal of the mesh.
- GYNECARE GYNEMESH™ should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.

WARNINGS

Patients who are on anticoagulation agents and undergoing surgery using GYNECARE GYNEMESH™ must have their anticoagulation therapy carefully managed.

- A digital rectal examination may be performed to detect possible rectal perforation.
- Cystoscopy may be performed to confirm bladder integrity or to detect possible bladder or ureteral perforation.
- Postoperatively, the patient should be advised to refrain from intercourse, heavy lifting, and/or exercise (e.g., cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Use GYNECARE GYNEMESH™ with care, and with attention to patient anatomy and to proper dissection technique, to avoid damage to vessels, nerves, bladder, bowel, and vaginal wall.

PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing GYNECARE GYNEMESH™.

- Avoid placing excessive tension on the mesh implant during placement.
- This product should only be used under the prescription of a licensed healthcare practitioner.
- In patients with compromised immune systems or other conditions that could compromise healing, the risks and benefits should be weighed carefully.
- Vaginal or urinary tract infection should be treated and alleviated prior to implantation.
- Acceptable surgical practice should be followed for GYNECARE GYNEMESH™ as well as for the management of infected or contaminated wounds. If GYNECARE GYNEMESH™ is used in contaminated areas, it must only be with the understanding that subsequent infection may require its removal.
- Prolapse repair may unmask pre-existing incontinence conditions.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.
- The use of this product with tissue adhesives is not recommended, as data are not currently available.

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, bleeding including hemorrhage, or hematoma, urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction, acute and/or chronic pain, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.
- Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, GYNECARE GYNEMESH™ may potentiate an existing infection.
- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- These adverse reactions may require surgical treatment.

- As with any surgery, one or more revision surgeries may be necessary to treat these complications.
- GYNECARE GYNEMESH™ is a permanent implant that integrates into the tissue. In cases in which the GYNECARE GYNEMESH™ needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Death

DESCRIPTION

GYNECARE GYNEMESH™ is constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE™ Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, LLC). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE™ mesh.

GYNECARE GYNEMESH™ is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling.

PATIENT FACTORS

Physicians should use their surgical experience and judgment to determine if GYNECARE GYNEMESH™ is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

PERFORMANCE

Animal studies show that implantation of PROLENE™ mesh elicits a minimal to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR USE (APPLICATION)

Trimming of the mesh should be performed at the surgeon's discretion to accommodate the patient's prolapse. Appropriate mesh fixation is required to minimize postoperative complications and their recurrence. The dissection and fixation technique and products used should follow the current

standard of care. It is recommended that sutures, staples, or other appropriate fixation devices be placed at least 6.5 mm (1/4") from edge of the mesh.

STERILITY

The product is sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of blood-borne pathogens to the patients and users. Do not use if package is opened or damaged. Discard all opened, unused mesh.

DISPOSAL

Dispense of the device and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE

Store at or below 25°C. Do not use after expiry date.

HOW SUPPLIED

GYNECARE GYNEMESH™ is available in single packets as sterile, clear sheets with blue stripes. Product is available in two sizes, 10 cm x 15 cm (4" x 6") or 25 cm x 25 cm (10" x 10").

Symbols Used on Labeling

	Do not reuse		Batch code
	Do not resterilize		Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Use by		Do not use if package is damaged
	Sterilized using Ethylene Oxide		Upper limit of temperature
	Consult instructions for use		Authorized Representative in the European Community
	Catalogue number		CE Mark and Identification Number of Notified Body. The product meets the essential requirements of the Medical Device Directive 93/42/EEC.
	Manufacturer		